

REMARKS

Reconsideration is requested.

Claims 1-15 and 17-25 are pending. Claims 18-25 have been added and find support throughout the specification. No new matter has been added.

The specification has been amended to include the attached Sequence Listing and the specification and claims have been revised to include sequence identifiers from the Sequence Listing. No new matter has been added.

Specifically, SEQ ID NOs:1-5 of the attached Sequence Listing describe human α -lactalbumin, bovine α -lactalbumin, human α -lactalbumin D87A, human α -lactalbumin D87N and human α -lactalbumin S70R, respectively.

The Examiner will appreciate that the amino acid sequences of human and bovine α -lactalbumin were known and described, for example, in Watanabe et al (Identification of Canine α -Lactalbumin, J. Vet. Med. Sci. 62(11): 1217-1219, 2000 (copy attached and listed on the attached PTO 1449 Form)) and Permyakov SE (2001), Protein Engineering 14(10) 785-789 (of record), which are noted in the present specification at paragraphs [0005], [0006] and [0030] of the U.S. Patent Office published version of the specification (i.e., U.S. Patent Application Publication No. 20050085416). The mutants of bovine α -lactalbumin (SEQ ID NOs:3-5) are further described, for example, on page 7, lines 25-27 and page 8, lines 2-4 of the present specification. No new matter has been added.

The claims have been amended to include sequence identifiers. Moreover, the claims include a recitation of a percent sequence similarity, as described at page 5,

lines 15-18 of the present specification. Further support for the above amendments can be found, for example, at page 6, lines 12-18, page 7, lines 29-33 and page 8, lines 2-4.

To the extent not obviated by the above amendments, the Section 112, first paragraph "written description", rejection of claims 1, 4, 5, 6, 9 and 10 is traversed. Reconsideration and withdrawal of the rejection are requested in view of the above and the following remarks.

The claims are submitted to be supported by an adequate written description.

The fragments of claims 1, 4 and 9 are required by the claims to form a biologically active complex and to contain the recited regions. The fragments of the claims are submitted to be supported by an adequate written description.

The variants of the claims are defined as being at least 70% identical to SEQ ID NOs: 1 or 2, forming a biologically active complex and containing the recited regions. The variants are described, for example, on page 7, lines 29-31, of the specification.

Moreover, page 5 of the specification describes variants of alpha-lactalbumin as polypeptides and proteins homologous to the human or bovine alpha-lactalbumin. The sequences of alpha-lactalbumin from various species are approximately 70% identical and any such sequence is described by the present specification and covered by the claims. The level of identity is further defined in one page 5, lines 15-18. The claims define variants as being at least 70% identical to human alpha-lactalbumin as defined by SEQ ID NO:1 or at least 70% identical to bovine alpha-lactalbumin as defined by SEQ ID NO:2.

The variants of the claims are believed to be supported by an adequate written description.

The cofactor of the claims is supported by an adequate written description. The cofactor of the claims is defined as a cofactor which stabilises the complex in a biologically active form. The cofactor other than C18:1:9 is part of a proviso, which defines that the cofactor may not be C18:1:9 in the specific embodiment where the complex comprises full length α -lactalbumin or a variant of α -lactalbumin in which the calcium binding site has been modified so that the affinity for calcium is reduced, or it is no longer functional. Thus "other cofactor" is a cofactor which stabilises the complex in a biologically active form and which is not C18:1:9 fatty acids in the specifically mentioned situation.

The Examiner is further requested to appreciate that the specification describes methods of evaluating the ability of cofactors to stabilise the complex in a biologically active form. See Example 1. An ordinarily skilled person would appreciate from the present specification that the applicants were in possession of the claimed invention at the time the application was filed. Moreover, the ordinarily skilled person would be able to make and use the claimed invention without undue experimentation. The applicants further note, for example, that paragraph [0087] of the USPTO published version of the specification describes that unsaturated cis fatty acids stimulate formation of biologically active complexes. Although the activity of the complexes formed by some of the tested fatty acids is lower than the activity of the complex comprising C18:1:9, the complexes are biologically active.

The claims are submitted to be supported by an adequate written description and withdrawal of the Section 112, first paragraph, rejection of claims 1, 4, 5, 6, 9 and 10 is requested.

The Section 112, second paragraph, rejection of claims 7, 9, 12 and 15 is obviated by the above amendments which has included reference sequence identifiers. Withdrawal of the rejection is requested.

The Section 112, second paragraph, rejection of claim 2 is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following.

As indicated above, the proviso of claim 1 states that when the complex comprises full length α -lactalbumin or a variant of α -lactalbumin in which the calcium binding site has been modified so that the affinity for calcium is reduced, or it is no longer functional, then the cofactor is other than C18:1:9 cis fatty acid. Claim 1 does not require that the complex necessarily includes a cofactor is other than C18:1:9 cis fatty acid. Claim 2, which is dependent on claim 1, defines a complex wherein the cofactor is C18:1:11 fatty acid and one of ordinary skill would appreciate that the complex of claim 2 does not include full length α -lactalbumin or a variant of α -lactalbumin in which the calcium binding site has been modified so that the affinity for calcium is reduced, or it is no longer functional. Claim 2 is definite and finds proper antecedent basis in claim 1.

The Examiner has objected to the drawings while indicating that the description of the drawings in the specification should be amended to overcome the objection. The above amendments to the specification are believed to be responsive to the Examiner's comments and to obviate the objection to the drawings. Withdrawal of the objection to the drawings is requested.

Claim 17 has been amended to obviate the objection to the same.

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The claims are submitted to be in condition for allowance and a Notice to that effect is requested. The Examiner is requested to contact the undersigned in the event anything further is required.

Respectfully submitted,

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